



WEST VIRGINIA INTEGRATED BEHAVIORAL HEALTH CONFERENCE

Creating Secure Medicine Return Programs to Reduce Misuse of Medicines in King County & Washington State

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Local Hazardous Waste Management Program in King County (WA)

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Local Hazardous Waste Management Program in King County (LHWMP)

Program Partners:

Public Health - Seattle & King County
King Co. Water and Land Resources Division
King Co. Solid Waste Division
Seattle Public Utilities
Sound Cities Association

Medicine Take-Back Activities since 2005

- Promoting programs: pilots, models, technical & financial assistance
- Education on safe storage & disposal
- Working on Local, State & Federal policy initiatives



Overview of Today's Presentation

- **Secure medicine return & Preventing medicine abuse, poisonings, and overdose deaths**
- **Voluntary medicine take-back programs & Barriers to a comprehensive system**
- **Recent action by King County Board of Health to adopt the Secure Medicine Return Regulations**
- **Explanation of Product Stewardship Approach**
- **Walk-through the Regulations requirements**
- **Q&A**

Secure Medicine Return Problem Statement

- Drug overdose deaths have surpassed car crashes as a leading cause of preventable death in King County.
- Medicines used in the home are the leading cause of poisonings, especially among children and seniors.
- Medicine take-back programs provide secure collection and destruction of unwanted medicines to protect public health and the environment.
- Currently, no sustainable financing for a medicine take-back system that meets community needs.



Epidemic: Responding to America's Prescription Drug Abuse Crisis

2013 National Drug Control Strategy:

1. Education of health providers and the public.
2. Expand prescription monitoring programs.
3. Safe drug disposal – increase return/take-back and disposal programs.
4. Effective enforcement to address “pill mills” and “doctor shopping.”



What are the options for disposal?

Flushing Medications:

- 20-33% of people still flush medications
- Sewer systems not designed to treat pharmaceuticals
- Studies find medicines in Puget Sound



Throwing Medications in the Trash:

- Trash cans are not secure
- Medicines enter the environment via landfill leachate
- Businesses are not allowed to put medicines in the trash



Voluntary Medicine Take-Back Programs

Secure AND environmentally sound...

Some
Law
Enforcement



Some
Pharmacies



Secure
Tracking &
Storage



Safe Disposal
by High
Temperature
Incineration



Barriers to a Comprehensive Medicine Take-back System in King County:

- **Challenges in collection of controlled substances** – help coming from new DEA draft regulation! authorizes take-back by retail pharmacies, manufacturers, drug distributors, and reverse distributors.
- **Convenience and access** – too few drop-off sites; too much of county unserved.
- **Financing** – lack of dedicated & adequate funding; very limited funding for education & promotion.
- **Lack of an efficient system** – no county-wide coordination.

DEA's Proposed Rule for Secure & Responsible Drug Disposal Act of 2010

December 2012 draft rule published; comment period ended February 2013. Waiting for final rule.

Controlled substances may be collected with all other medicines through 3 take-back methods under specific security protocols.

Collection receptacles (i.e. drop-off boxes) and **mail-back programs** may be operated by authorized **retail pharmacies, drug manufacturers, drug distributors, reverse distributors, and law enforcement.**

Take-back events may be conducted by law enforcement only.

King County Board of Health

Legislative body that sets county-wide policies and regulations to protect and promote the health of King County residents.



Board Chair
Councilmember Joe McDermott



Boardmember
Mayor David Baker

Subcommittee on Secure Medicine Return

Board Chair Joe McDermott, Boardmembers David Baker, Richard Conlin and Dr. Bud Nicola, and Public Health Director David Fleming

- July – October 2012, collected stakeholder input (pro & con).
- October 2012 - April 2013, policy discussions
- Public hearings held May 16th and June 20th, 2013
- Secure Medicine Return Regulations adopted on June 20, 2013. Effective July 20, 2013.

Board of Health Subcommittee on Secure Medicine Return

Stakeholders included:

- Current providers or regulators of medicine take-back activities
- Pharmaceutical industry
- Organizations representing impacted residents
- Substance abuse professionals
- Health and medical organizations
- Community organizations
- Environmental groups

Product Stewardship Approaches for Medicine Take-back

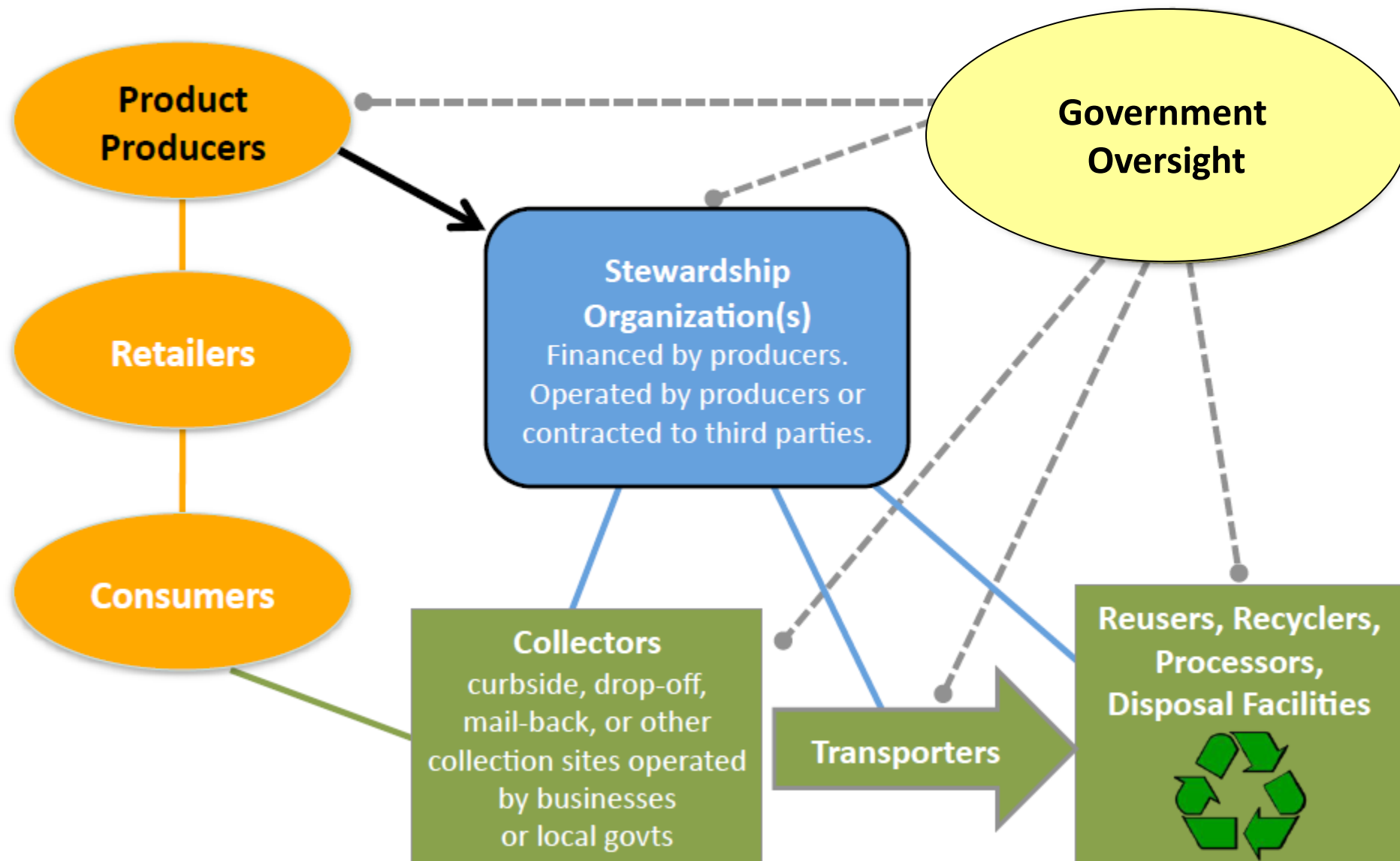
Pharmaceutical manufacturers provide medicine return systems in B.C., Manitoba, Ontario, France, Spain & Mexico.

“**Product stewardship**” is the act of minimizing health, safety, environmental, social impacts, while maximizing economic benefits of a product and its packaging throughout all lifecycle stages.



Generic Example of Product Stewardship Relationships:

all key stakeholders have roles in product management.



Examples of Producer Take-Back Programs for Other Hazardous Products

- Rechargeable Batteries
- Paint
- Electronic Waste
- Auto Switches
- Mercury Lighting & Thermostats
- Cell Phones



Product Stewardship Legislation for Pharmaceuticals in the U.S.

- Federal legislation introduced in 2011 (HR 2939 – Slaughter); no action taken; potential reintroduction in 2013 or 2014.
- State-level legislation proposed in 8 states in recent years (CA, FL, ME, MD, MN, NY, OR, PA, WA); none have passed yet.
- San Francisco, City & County, considered Safe Drug Disposal ordinance in 2010. Legislation tabled when PhRMA and Genentech agreed to grant funds for a city-operated pilot program.
- Alameda County, CA passed a Safe Drug Disposal Ordinance in July 2012. Pharma associations sue.

Secure Medicine Return Regulations Adopted by King County Board of Health - Overview

- Drug producers are required to finance and provide the secure medicine return system.
- Residents will bring leftover, expired, and unneeded medicines to secure drop boxes in retail pharmacies or law enforcement offices throughout the county.
- If a drop-off site is not available in a specific area then periodic collection events or prepaid return mailers will be provided.
- Collected medicines are securely handled, transported and disposed of according to federal & state laws and policies.
- PHSKC and LHWMP provide oversight to ensure safety and compliance.

Secure Medicine Return Regulations; “Drug Producers” & Stewardship Plans

Operation of the system by drug producers:

Drug producers develop a stewardship plan to meet the requirements and standards of the Regulations.

“**Drug Producers**” are the companies that “manufacture” the “covered drug”.

Does not include:

- Compounding pharmacists preparing drugs for individual patients.
- Drug retail brand holders unless it is not possible to identify the manufacturer of the store brand drug.

At least 167 pharmaceutical companies sell medicines for residential use in Washington State.

Sales in King County alone are > \$1.1 billion annually.

Secure Medicine Return Regulations: “Covered Drugs”

Medicines accepted for return:

Prescription and over-the-counter drugs from residential sources, including controlled substances.

Not accepted:

- Over-the-counter drugs that are also regulated as cosmetics.
- Vitamins and supplements.
- Specific situations where drugs have established take-back systems.



Secure Medicine Return Regulations; Collection System Requirements

“Service convenience goal”

- All pharmacies and law enforcement agencies that volunteer to serve as collectors can participate.
- Minimum number of drop-off sites provided or provide periodic collection events and/or prepaid mailers.
- Prepaid, preaddressed mailers can be requested for home bound or disabled residents.
- Drug handling must conform to all applicable federal and state laws, regulations, and policies, including the DEA and the Washington State Board of Pharmacy.

Overview of Secure Medicine Regulations:

Final Disposal of collected medicines

- Disposal at a properly permitted hazardous waste facility, unless permission is granted to use a large municipal waste combustion facility (e.g. Waste-to-Energy facility) because of cost or logistical barriers.

Consistent with EPA's disposal recommendations for collected household medicines (Sept. 2012).

- Use of alternative disposal technologies may also be approved.



Secure Medicine Return Regulations: Promotion & Evaluation

Required promotion by drug producers:

- Promote safe storage of medicines and use of the medicine return system
- Materials for pharmacies, health care facilities, and others
- Website and toll-free number
- Develop clear instructions on use of secure drop boxes and a readily recognizable, consistent drop box design

Required evaluation by drug producers:

- Annually report pounds of medicines collected & evaluate the effectiveness of program promotion
- Conduct survey of residents after the first program year, and again at years five and nine

Secure Medicine Return Regulations: Cost Responsibilities

Drug producers are responsible for costs of:

- Collection supplies, prepaid mailers, collection events
- Transporting collected medicines and final disposal
- Program promotion and evaluation
- Administrative costs
- Fees to PHSKC to reimburse costs of oversight

Voluntary collectors will provide in-kind staff time at drop-off sites.

LHWMP will assist with start-up costs of secure drop boxes and with education/promotion.

No visible fee on medicines at purchase or return.

Secure Medicine Return Regulations: Oversight & Enforcement

Public Health—Seattle & King County & the Local Hazardous Waste Management Program

- Review and approval of the stewardship plan(s), plan changes, and plan updates
- Monitoring of plan operations
- Inspections as needed
- Review of annual reports

Enforcement: written warnings and civil penalties of up to \$2,000 per day.

Agency cost recovery through fees collected from each stewardship plan, paid by drug producers.

Secure Medicine Return Regulations: Key Implementation Deadlines

Program start expected ~18 months from adoption of the Regulations on June 20, 2013.

By December 20, 2013 – Each drug producer selling covered drugs in or into King County must indicate their intent to participate in a stewardship plan.

By March 20, 2014 – Drug producers must notify all retail pharmacies and law enforcement agencies in the county of the opportunity to participate as a drop-off site.

By June 20, 2014 – Drug producers must submit a proposed stewardship plan for review.

Stewardship plans must start within 3 months of approval.

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Secure Medicine Return Regulations

website: www.KingCountySecureMedicineReturn.org

to receive email updates subscribe to: <http://bit.ly/securemeds>

Information & Resources on Medicine Take-back in WA
& Product Stewardship: www.TakeBackYourMeds.org

